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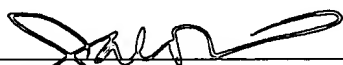
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Respectfully submitted,

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Title of invention

"Bone grafting materials"
(Luuta korvaavat materiaalit)

Täten todistetaan, että oheiset asiakirjat ovat tarkkoja jäljennöksiä patentti- ja rekisterihallitukselle alkuaan annetuista selityksestä, patenttivaatimuksista, tiivistelmästä ja piirustuksista.

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Bone grafting materials

Field of the invention

The present invention relates to bone grafting materials prepared from glass fibers, preferably bioactive glass fibers by sintering them to form a porous three dimensional block for filling in a defect or hollow portion of bone. In more detail the present invention relates to a block prepared by sintering glass fibers, preferably bioactive glass fibers together to form a porous three dimensional block. The prepared block is an ideal scaffold for new tissue (e.g. bone or cartilage) formation to occur due to the osteoconductive properties the bioactive glass fibers have.

Background of the invention

In surgical and orthopaedic treatments, prosthesis operations are often required for filling in defects or hollow portions of bone resulting from e.g. fracture of bone or surgical removal of bone tumor. Also in the field of dental surgery, similar denture operations are often required for filling in spoilt void portions in maxilla or mandible resulting from pyorhoea alveolaris. It has been a common practice to harvest bone from donor site, for example from the iliac crest of the patient to fill up the defect or hollow portion of bone and thereby to promote the regeneration of the bone tissue. However, to perform such an operation normal, undamaged bone tissue must be picked up from an unspoilt portion. This operation causes additional pain to the patient and is in addition a very troublesome procedure. Moreover, when the volume of the defect or void in the patient's bone is large, the amount of bone obtainable from the patient's own body is not always adequate to fully fill in the defect or void. In such cases it is inevitable to use a substitute for the patient's own bone tissue. Even though the same sort of bone tissue has been used as the substitute there still remains the problem that the implanted substitute is rejected by the living tissue due to the foreign body rejection reaction. For these reasons the post-operation recovery of the defect is not always satisfactory. Accordingly, such an operation has not yet been recognized as fully satisfactory in practice.

There is therefore a demand for an artificial material which has excellent compatibility with living tissues when filled in a defect or hollow portion of bone to facilitate formation of bone within and at the vicinity of the defect and to promote repair and recovery of the structure and function of the once damaged bone tissue.

A variety of metal alloys and organic materials have hereto been used as the substitute for the hard tissues in the living body. However, it has been recognized that these materials tend to dissolve or otherwise deteriorate in the environment of living tissue and that these materials are toxic to the living body and cause so called foreign body reaction. Ceramic materials have been used up to date due to their excellent compatibility with living body and due to the fact that they are free of the aforementioned difficulties. Artificial bones and teeth have been developed from ceramic materials, particularly alumina, carbon or tricalcium phosphate or from sintered mass or single crystal of hydroxyapatite which have superior compatibility with living body. These embodiments have attracted a good deal of the public attention.

However, the conventional ceramic implant materials have a common disadvantage in that they are inherently too hard and brittle. Therefore these known ceramic materials are not fully satisfactory in practical use. A defect in bone has also been attempted to be filled with a sintered ceramic block or a ceramic block of single crystal form. However, since uneven gaps or interstices are formed between the block and the bone tissue, the object of fully filling in the void in the bone cannot be attained. On the other hand, when alumina is used as the filler, it acts as a stimulant to cause absorption of bone at the vicinity of the implanted filler due to the fact that alumina is much harder than the bone tissue. The use of ceramic materials has not yet been in stage of practical application, accordingly. Furthermore, it has not been clarified what are the properties a ceramic material should have to suppress the foreign body rejection reaction and to improve the compatibility with living body as well as promote formation of new bone.

Heimo Ylänen (Doctoral Thesis, Turku, Finland 2000) has studied bone ingrowth into porous bodies made by sintering bioactive glass microspheres. He has found out that rigid porous bioactive glass implants provide an environment which promotes throughout the whole implant an extended incorporation of new bone into space between the sintered bioactive microspheres. As a result the implant is quickly and firmly bonded to the host bone. In the studies is also noted that the in vitro rate of the reactions inside the porous glass implant is higher than the non-porous glass rods made from the same bioactive glass. The block sintered from bioactive glass spheres is brittle and breaks easily if load is applied to it. Another drawback with blocks sintered

from glass spheres is that the porosity is considerably low and this affects bone forming properties in this device.

Publication WO 00/35509 discloses a porous textile product made from bioactive glass and a weakly bioactive glass. Several ways to produce the textile product are suggested in the publication but there is no suggestion of sintering the bioactive glasses together.

Finnish patent 103 715 discloses a composite made of bioactive material A and of non-bioactive material B or weakly bioactive material B and the materials have been sintered together to a porous composition. According to the patent particles A and B are rounded, preferably spherical. In the Finnish patent 103 715 there is no suggestion to use glass fibers for preparing the composition.

Finnish patent application 923 561 discloses bioactive glass compositions and preparation of implants from the filaments of the said bioactive glass compositions. However, there is no teaching in the publication to sinter the filaments together.

In publication WO 97/31661 is described an osteogenic device which comprises a shapeable porous carrier body selected from hydroxyapatite, tricalcium phosphate, bioactive glass and biocoral. There is no teaching in the publication of using bioactive glass fiber.

US patent 6 054 400 discloses an invention which relates to novel bioactive glasses with a large working range and controlled durability. The publication discloses also the use of the bioactive glasses for tissue bonding purposes in the medical or dental field, for use in biotechnology, for controlled release of agents and for tissue guiding. The filling material comprises bioactive glass in crushed form or as spherical granules. There is no suggestion in the US patent to use glass fibers.

US patent 5 429 996 concerns a bone grafting material for use in medicine which is glass wool having the following composition 40 - 62 % (w/w) SiO_2 , 10 - 32 % (w/w) Na_2O , 10 - 32 % (w/w) CaO , 0 - 12 % (w/w) P_2O_5 , 0 - 12 % (w/w) CaF_2 , 0 - 21 % (w/w) B_2O_3 . The glass wool has a mean diameter of 100 μm or less. There is no suggestion of using sintered glass fibers in this publication.

In US patent 5 468 544 are disclosed composite materials using bone bioactive glass and ceramic fibers. In more detail in the patent is described composite structures that incorporate a bioactive material in a polymer

matrix along with a structural fiber. The polymeric matrix used is a non-bioabsorbable polymeric matrix, for example polysulphone, PEEK or PEKK and the structural fiber is a carbon fiber.

US patent 4 735 857 describes a fiber glass for filling in a defect or
 5 hollow portion of bone. The fiber glass comprises calcium phosphate as a main ingredient and has a negative zeta potential. The fiber glass is of long filament form or staple fiber form and the long filament form may be woven to form a woven filler, for example a cloth or gauze. In the US patent there is no suggestion of sintering the fibers.

10 In US patent 5 914 356 is described a woven filler for filling in a defect or hollow portion of bone. The woven filler is prepared by weaving fiber glass filaments which fiber glass consists essentially of calcium phosphate and has a negative zeta point as well, and of an inorganic oxide. The inorganic oxide can be alumina, silica, sodium oxide, iron oxide, magnesium oxide, ka-
 15 olin or a mixture thereof. There is no teaching of sintering the glass fibers in this patent.

US patent 5 711 960 describes an implant material which comprises as a base material a biocompatible bulk structure of a tri-axial or more three-
 20 dimensionally woven fabric of organic fibers, a tri-axial or more three-dimensionally knitted fabric of organic fibers or combination thereof.

US patent 4 904 257 discloses a method of filling a void in a bond which comprises filling the void with a fibrous bone comprising fibers containing intact hydroxyl apatite, water-soluble binder and water.

M.A. De Diego et al. (Tensile Properties of Bioactive Fibers for Tis-
 25 sue Engineering Applications, Journal of Biomedical Materials Research, 2000, Vol. 3,199 - 203) have studied tensile properties of bioactive fibers for tissue engineering applications. The tested material was 45S5 Bioglass® which is a 4-component, melt-derived bioactive glass. In the study tensile strength, elongation to fracture and Weibull's moduli of 45S5 Bioglass® is re-
 30 ported.

It is also known in the art that the fabrication of 3D scaffolds for skeletal reconstruction from bioceramics and biopolymers has been studied.

Brief d scription of the invention

35 Surprisingly it has been found out that by sintering glass fibers, preferably bioactive glass fibers the problems related to the prior art solutions can be solved. An object of the present invention is thus to provide a porous

bioactive scaffold, manufactured from glass fibers, preferably bioactive glass fibers by sintering for filling in a defect or hollow portion of bone to solve the above problems. The porous scaffold can also be prepared by sintering other bioceramic fibers for example HA (hydroxy apatite) fibers. The objects of the invention are achieved by an arrangement which is characterized by what is stated in the independent claims. The preferred embodiments of the invention are disclosed in the dependent claims.

The invention is based on the idea of manufacturing a porous scaffold by sintering glass fibers. In a preferred embodiment of the present invention bioactive glass fibers are sintered together to form a scaffold. Bioactive glass has an excellent compatibility with the living body without causing foreign body rejection reaction, and which promotes early formation of new bone and unifies integrally with the growing hard tissue of the living body.

Another object of the present invention is to provide a scaffold promoting bone formation reaction in the area filled with the sintered glass fiber block, preferably with the bioactive glass fiber block to realize early remedy and recovery of the structure and function of the once damaged bone tissue.

Another object of this invention is to provide a glass fiber, preferably a bioactive glass fiber scaffold for filling in a defect or hollow portion of bone and maintain the space, even though load is applied on the scaffold.

Another object of this invention is to provide a method for preparing the porous scaffold of the present invention by sintering glass fibers, preferably bioactive glass fibers.

The above and other objects of the invention will become apparent from the following detailed description of the invention.

An advantage of the invention is that by sintering glass fibers, preferably bioactive glass fibers instead of glass microspheres a better strength of the scaffold is attained. Also a greater porosity percentage is received when sintering glass fibers compared to the spheres. The healing of the bone is faster because the proportion of the bone in the scaffold is larger compared to the scaffolds prepared from glass spheres. Another advantage of the present invention is that if a dissolvable glass is used the final dissolving of the scaffold in the tissue is effected by the diameter of the fibers. The smaller the diameter of the fibers the faster the scaffold is dissolved in the tissue. Another advantage of the present invention is that there is a greater amount of reacting surface in the scaffold when the scaffold is prepared by sintering glass fibers,

preferably bioactive glass fibers compared to the scaffold prepared by sintering glass spheres. By using a scaffold prepared by sintering glass fibers it is possible to adjust the retaining time of the scaffold in the tissue to an appropriate level.

5 In the healing of a wound the wound stability is a critical factor. Wound stability seems critical for example to the outcome of periodontal healing. If tensile forces acting on the wound margins can be controlled by wound stabilizing measures such as grafting and implant materials, specific flap adaptation and suturing techniques, or barrier membranes; the root surface-
10 gingival flap interface may heal with connective tissue repair. Another advantage of the present invention is that when scaffolds prepared by sintering glass fibers or bioactive glass fibers are used, it seems that there are less tensile forces on the wound margins and a greater wound stability is reached. This results in a faster wound healing.

15 **Brief description of the drawings**

In the following the invention will be described in greater detail by means of preferred embodiments with reference to the attached drawings, in which

Figure 1 shows a porous bioactive scaffold attached to a polymeric
20 film and its application in the use of reconstructing alveolar bone.

Figure 2 shows the use of the porous bioactive scaffold attached to a polymeric film in filling in a bone defect.

Figure 3 shows a mat of the sintered bioactive glass fibers attached to a membrane.

25 Figure 4 illustrates the sintering of the bioactive glass fibers in a mould form.

Detailed description of the invention

Bioactive material is a material which has been designed to induce specific biological activity.

30 Bioactive glass means in this context any glass or glass ceramic that displays the characteristics of bioactivity. Bioactive glass is an amorphous solid that is not intrinsically adhesive and that is capable of forming a cohesive bond with both hard and soft tissue when exposed to appropriate in vivo and in vitro environments, such as simulated body fluid or tris-hydroxymethylamino-

methane buffer, by developing a surface layer of hydroxycarbonate apatite by release of ionic species from the bulk material.

Bioceramic is any ceramic, glass or glass ceramic that is used as a biomaterial and a ceramic which upon implantation is transformed into less soluble minerals. Bioactive glass is an example of a bioceramic material.

Osteoconduction is a process of passively allowing bone to grow and remodel over a surface. In osteoconduction the implant provides a bio-compatible interface along which bone migrates.

Porosity means in this context the volume percentage of air in a three dimensional scaffold.

Scaffold is a porous structural device which allows living tissues to grow into it. Scaffold forms a base which serves as a guide for tissue growth.

In the present invention glass fibers, preferably bioactive glass fibers are first formed e.g. by using melt spinning technique. The fibers are then chopped into desired length. Lump of fibers is then heated in an oven so that fibers are sintered together and a porous three-dimensional block is formed. The properties of block, i.e. porosity, pore size and compressive strength can be adjusted to desired level by adjusting fiber diameter, sintering time and sintering temperature. The porous three-dimensional block can also be prepared by sintering bioceramic fibers.

In another embodiment of the present invention the sintering of the glass fibers, preferably bioactive glass fibers is performed under load. This means that a weight is applied onto the fibers during the sintering. Sintering under load results in a more homogenous structure of the scaffold.

By sintering glass fibers, preferably bioactive glass fibers a porous, osteoconductive scaffold can be formed. By optimising the processing parameters the degree of porosity can be controlled. Porosity as high as 90 vol-% can be achieved when the glass fibers are sintered together as described in this invention. Compression strength of the scaffold can be optimised to be from 5 to 25 MPa, preferably over 20 MPa, which is stated to be the requirement for load bearing purposes of the scaffold. The optimisation is done by increasing fiber diameter, sintering temperature and sintering time. A sintered body from glass fibers, preferably bioactive glass fibers is considerably soft and by altering the processing parameters different kind of products with different kind of properties can be formed.

In a preferred embodiment of the present invention a porous scaffold made by sintering glass fibers, preferably bioactive glass fibers can be attached into a biocompatible polymeric film, so that the porous scaffold has a barrier property on its side. This apparatus can be used for example with
 5 guided bone regeneration where barrier effect is required to avoid soft tissue ingrowth in the area where new bone formation is required. Another application of the apparatus is in regeneration of cartilage tissue. The porous scaffold sintered from glass fibers, preferably from bioactive glass fibers is able to form a base into which cartilage tissue can grow and the barrier side separates the
 10 new forming cartilage tissue and the liquids inside the joint in confusion.

The biocompatible film is prepared for example of polyglycolide, polylactide, poly- β -hydroxybutyric acid, polydioxanone, polyvinylalcohol, polyesteramine, their copolymers or polymer blends thereof.

In another preferred embodiment of the present invention the glass
 15 fibers, preferably bioactive glass fibers are sintered together under compression load. The compression load used is approximately 10 kPa.

In another preferred embodiment of the present invention bioactive agents can be used in combination with the sintered porous scaffold to promote new tissue, e.g. bone formation. In such a case the porous scaffold
 20 made from bioactive glass fibers acts as carrier for bioactive agents. The biologically active agent is selected from the group consisting of anti-inflammatory agents, antibacterial agents, antiparasitic agents, antifungal agents, antiviral agents, anti-neoplastic agents, analgesic agents, anaesthetics, vaccines, central nervous system agents, growth factors, hormones, antihistamines, osteoinductive agents, cardiovascular agents, anti-ulcer agents, bronchodilators,
 25 vasodilators, birth control agents, fertility enhancing agents and polypeptides. Preferably the bioactive agents are bone morphogenic proteins (BMP).

In another preferred embodiment of the present application the glass fibers, preferably the bioactive glass fibers are first coated with biocompatible polymer prior to the sintering. The fibers are chopped and then coated
 30 fibers are sintered to form a three dimensional scaffold. In this case the scaffold has reasonable elastic performance and can be applied in cases where elastic performance is required from the scaffold.

The bioactive glass used in this invention has the following composition
 35 53 - 60 wt-% SiO_2 , 0 - 34 wt-% Na_2O , 1 - 20 wt-% K_2O , 0 - 5 wt-% MgO , 5 - 25 wt-% CaO , 0 - 4 wt-% B_2O_3 , 0,5 - 6 wt-% P_2O_5 , provided that $\text{Na}_2\text{O} +$

$K_2O = 16 - 35$ wt-%; $K_2O + MgO = 5 - 20$ wt-% and $MgO + CaO = 10 - 25$ wt-%. Preferably the bioactive glass has the following composition 53 wt-% SiO_2 , 6 wt-% Na_2O , 12 wt-% K_2O , 5 wt-% MgO , 20 wt-% CaO , 0 wt-% B_2O_3 and 4 wt-% P_2O_5 . The preferred composition is referred in this context as glass 13-93
5 prepared by Abmin Technologies.

The chopped fibers have a length from 2 to 30 mm, preferably the length of the fibers is approximately from 5 to 15 mm. By controlling the length of the fibers the size of the pores can be adjusted to a desired level.

The fibers have a diameter of 0,010 - 1,0 mm, preferably from 0,030
10 to 0,300 mm. By altering the diameter of the fibers the rate of dissolving can be controlled. Lower sintering temperatures can be used for fibers with smaller diameter and a more porous scaffold is received. By altering the processing parameters the properties of the scaffold can be adjusted to desired level and for example a scaffold which is easily formable for example with a knife can be
15 prepared.

Sintering temperatures of the present invention for bioactive glass fibers are from 300 °C to 1500 °C, preferably from 600 °C to 700 °C, most preferably from 630 °C to 680 °C.

When fibers coated with biocompatible polymers are sintered, the
20 sintering temperature depends on the softening point of the coat polymer. When biocompatible polymers are used the sintering temperature is from 50 °C to 300 °C, preferably from 100 °C to 200 °C.

Suitable biocompatible polymers are for example polyglycolide, polylactide, poly- β -hydroxybutyric acid, polydioxanone, polyvinylalcohol, poly-
25 esteramine, their copolymers and polymer blends thereof.

The thickness of the polymer coating on the fibers is from 1 to 200 μm , preferably from 5 to 30 μm .

The preferred sintering time in this invention when sintering glass fibers, preferably bioactive glass fibers is from 1 to 120 minutes, preferably from
30 5 to 30 minutes. The sintering time of the present invention when sintering glass fibers, preferably bioactive glass fibers coated with polymers is from 1 to 120 minutes, preferably from 5 to 30 minutes.

By altering the sintering parameters, i.e. sintering temperature, sintering time, length of the fibers, diameter of the fibers, the properties of the
35 formed scaffold can be adjusted to desired level. For example the compression strength of the scaffold can be increased when thicker fibers and a higher

sintering temperature are used. And the formability of the scaffold can be improved when thinner fibers are used and the sintering temperature is in the lower end of the softening area of the glass.

By sintering glass fibers, preferably bioactive glass fibers a scaffold
5 is formed which has a porosity of 5 to 95 volume-%, preferably from 50 to 90 volume-%.

The load bearing capacity of the prepared scaffold is characterised by the compression strength. When sintering glass fibers, preferably bioactive glass fibers, a scaffold is obtained which has excellent load bearing properties.
10 The compression strength of the scaffold of this invention is from 5 to 25 MPa, preferably over 20 MPa.

Figure 1 shows one preferred embodiment of the present invention where sintered porous glass fiber, preferably bioactive glass fiber scaffold 1 is attached to a polymeric film 2 e.g. by sintering or by processing under heat and pressure. This film with porous scaffold can be used e.g. as a membrane
15 in Guided Bone Regeneration procedures or Guided Tissue Regeneration procedures, where the membrane is used as a barrier to avoid soft tissue in-growth, to enhance the regeneration of bone tissue (or periodontal tissues). Figure 1 also shows that the film 2 which has a scaffold 1 attached to it can be bent and formed into desired shape. Figure 1 illustrates an example of the use of the scaffold 1 and the film 2 in reconstructing a defect in alveolar bone
20 3. The scaffold 1 and the film 2 are attached to the defect with small nails 4.

Figure 2 shows an example of the use of the scaffold 1 and the membrane 2 in filling in a defect in a bone 5. The scaffold and the film is
25 attached to the bone with small nails 4.

Figure 3 illustrates another preferred embodiment of the present invention in which a sintered mat of the glass fibers (7), preferably a sintered mat of the bioactive glass fibers is attached to a membrane (6). This device can be used in guided tissue regeneration or in guided bone regeneration.

In one embodiment of the present invention, as illustrated in Figure 4, the sintering of the glass fibers 8, preferably bioactive glass fibers is performed in a mould form 9 and a three dimensional scaffold of desired form is then obtained. When a three dimensional scaffold is obtained there is no need to machine the scaffold after the sintering of the fibers.
30

It will be obvious to a person skilled in the art that, as the technology advances, the inventive concept can be implemented in various ways. The
35

invention and its embodiments are not limited to the examples described above or below but may vary within the scope of the claims.

Examples

Example 1

5 Bioactive glass fibers were formed from glass 13-93 (prepared by Abmin Technologies) by melt spinning. The diameter of the fibers was 0,175 mm (+/- 0,025 mm). Fibers were then chopped to a length of 10 mm (+/- 2 mm) by using scissors.

10 While chopping the fibers, the pieces of glass fiber disintegrated and formed an "open" huddle. Chopped fibers were placed on to a steel plate and the plate with glass fibers was placed into a furnace. The furnace was slowly heated up to a temperature of 655 °C. The temperature of 655 °C was retained for 30 minutes and after that the furnace was cooled down.

15 From the obtained porous block three rectangular blocks were shaped by saw in order to measure the porosity and compression strength of the blocks.

The outer dimensions and the weight of each block were measured. The calculated mean porosity of the blocks was 26 vol-% glass (+/- 5 %) and 74 vol-% of air.

20 The compression strength of the blocks were measured by using Instron materials testing machine. The mean strength of 24,4 MPa (Standard deviation 3,8 MPa) was obtained.

Example 2

25 Bioactive glass fibers were formed from glass 13-93 by melt spinning. The diameter of the fibers was 0,075 mm (+/- 0,025 mm).

Fibers were then chopped to the length of 15 mm (+/- 2 mm) by using scissors. Chopped fibers were placed on to a steel plate and the plate with glass fibers was placed into a furnace. The furnace was slowly heated up to a temperature of 650 °C and the temperature was retained there for 30 minutes after which the furnace was cooled down.

30 From the obtained porous block three rectangular blocks were shaped with a surgical knife in order to measure porosity.

The outer dimensions and the weight of each block were measured. 35 The calculated mean porosity of the blocks was 11 vol-% glass (+/- 7 %) and 89 vol-% of air.

Exempl 3

Bioactive glass fibers from glass 13-93 with diameter of 0,1 mm (+/- 0,03 mm) were formed by melt spinning. Formed fibers were coated with viscous solution, which contained biodegradable polymer polylactide (PLA) (70L/30DL) and chloroform as a solvent. Fibers were dipped into the solution and as soon as the solvent evaporated the fibers were winded up with spinning roll.

Coated fibers were chopped by using scissors into a length of 15 mm (+/- 2 mm). Chopped fibers were placed on to a steel plate and the plate with glass fibers was placed in a furnace. The furnace was slowly heated up to a temperature of 140 °C for 5 minutes after which the furnace was cooled down. The obtained body had porosity of approximately 15 vol-% glass, 2 vol-% of polymer and 82 vol-% of air. The body was slightly flexible and did not break when bent.

Example 4

A porous block was formed from bioactive glass fibers as expressed in example 1 and the block was machined to have cylindrical shape with diameter of 15 mm and height of 10 mm. A polymeric film (made of polylactide) with thickness of 0,5 mm was formed by compression molding from extruded billet. From the compressed film a circular shape with diameter of 30 mm was cut.

The circular polymeric film was then attached to the porous block formed from bioactive glass fibers by using compression moulding. The plates of compression moulding machine were heated to the temperature of 180 °C. The parts were placed between the hot plates so that the porous block was placed right into middle of polymeric film. After 3 minutes pressure of 1 bar was applied and cooling unit was then turned on.

After the plates were cooled down to 30 °C, the obtained device was removed from the press. In the device obtained this way the block as firmly attached to the polymer film.

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Claims

1. A porous scaffold (1), **characterized** in that the scaffold is formed by sintering glass fibers.
2. A porous scaffold (1) according to claim 1, **characterized**
5 in that the scaffold is formed by sintering bioactive glass fibers.
3. A porous scaffold (1), **characterized** in that the scaffold is formed by sintering glass fibers coated with biocompatible polymer or polymers, their copolymers or polymer blends thereof.
4. A porous scaffold (1) according to claim 3, **characterized**
10 in that the scaffold is formed by sintering bioactive glass fibers coated with biocompatible polymer or polymers, their copolymers or polymer blends thereof.
5. A porous scaffold (1) according to claim 3 or 4, **characterized**
15 in that the biocompatible polymer is / polymers are selected from the group consisting of polyglycolide, polylactide, poly- β -hydroxybutyric acid, polydioxanone, polyvinylalcohol, polyesteramine, their copolymers and polymer blends thereof.
6. A porous scaffold (1) according to any one claims 3 to 5, **characterized**
20 in that the thickness of the coating is from 1 to 200 μ m, preferably from 5 to 30 μ m.
7. A porous scaffold (1) according to any one of the preceding claims, **characterized** in that the fibers have the length from 2 to 30 mm, preferably from 5 to 15 mm.
8. A porous scaffold (1) according to any one of the preceding
25 claims, **characterized** in that the fibers have a diameter in the range of 0,010 - 1,0 mm, preferably 0,030 - 0,300 mm.
9. A porous scaffold (1) according to any one of the preceding claims, **characterized** in that the porosity of the scaffold is from 5 to 95 vol-%, preferably from 50 to 90 vol-%.
- 30 10. A porous scaffold (1) according to any one of the preceding claims, **characterized** in that the compressive strength of the porous scaffold is from 5 to 25 MPa, preferably over 20 MPa.
11. A porous scaffold (1) according to any one of the preceding
35 claims, **characterized** in that the scaffold is attached into a biocompatible polymeric film.

12. A porous scaffold (1) according to claim 11, **characterized** in that the biocompatible polymeric film (2) comprises a polymer or polymers selected from the group of polyglycolide, polylactide, poly- β -hydroxybutyric acid, polydioxanone, polyvinylalcohol, polyesteramine, their copolymers and polymer blends thereof.

13. A method for preparing a porous scaffold (1) **characterized** in that the scaffold is formed by sintering glass fibers.

14. A method according to claim 13 **characterized** in that the porous scaffold (1) is formed by sintering bioactive glass fibers.

15. A method according to claim 13 or 14, **characterized** in that the glass fibers are sintered together at the temperature from 300 to 1500 °C, preferably from 600 to 700 °C, most preferably from 630 to 680 °C.

16. A method for preparing a porous scaffold (1) **characterized** in that the scaffold is formed by sintering glass fibers coated with biocompatible polymer or polymers, their copolymers or polymer blends thereof.

17. A method according to claim 16 **characterized** in that the porous scaffold (1) is formed by sintering bioactive glass fibers coated with biocompatible polymer or polymers, their copolymers or polymer blends thereof.

18. A method according to claim 16 or 17, **characterized** in that the glass fibers coated with a polymer or polymers are sintered together at the temperature from 50 to 300 °C, preferably from 100 to 200 °C.

19. A method according to any one of claims 13 to 18, **characterized** in that the glass fibers comprise bioactive glass having a composition of 53 - 60 wt-% SiO_2 , 0 - 34 wt-% Na_2O , 1 - 20 wt-% K_2O , 0 - 5 wt-% MgO , 5 - 25 wt-% CaO , 0 - 4 wt-% B_2O_3 , 0,5 - 6 wt-% P_2O_5 , provided that $\text{Na}_2\text{O} + \text{K}_2\text{O} = 16 - 35 \text{ wt-\%}$; $\text{K}_2\text{O} + \text{MgO} = 5 - 20 \text{ wt-\%}$ and $\text{MgO} + \text{CaO} = 10 - 25 \text{ wt-\%}$.

20. A method according to any one of claims 13 to 19, **characterized** in that the glass fibers comprise bioactive glass having a composition of 53 wt-% SiO_2 , 6 wt-% Na_2O , 12 wt-% K_2O , 5 wt-% MgO , 20 wt-% CaO , 0 wt-% B_2O_3 and 4 wt-% P_2O_5 .

21. A method according to any one of claims 13 to 20, **characterized** in that the sintering time is from 1 to 120 minutes, preferably from 5 to 30 minutes.

22. A method according to any one of claims 13 to 21, **characterized** in that the fibers are sintered together under compressive load.

23. A method according to any one of claims 13 to 22, **characterized** in that the fibers (8) are sintered together in a mould form (9).

5 24. A method according to any one of claims 13 to 23, **characterized** in that the fibers are sintered to form a mat (7) which is attached to a membrane (6).

25. The use of a porous scaffold (1) according to any one of the preceding claims, **characterized** in that the scaffold is used as a carrier for bioactive agents.

26. The use of a porous scaffold (1) according to claim 25, **characterized** in that the bioactive agent is selected from the group consisting of anti-inflammatory agents, antibacterial agents, antiparasitic agents, antifungal agents, antiviral agents, anti-neoplastic agents, analgesic agents, 15 anaesthetics, vaccines, central nervous system agents, growth factors, hormones, antihistamines, osteoinductive agents, cardiovascular agents, anti-ulcer agents, bronchodilators, vasodilators, birth control agents, fertility enhancing agents and polypeptides.

27. The use of a porous scaffold (1) according to claim 25 or 26, 20 **characterized** in that the bioactive agent is bone morphogenetic protein.

28. The use of a porous scaffold (1) according to any one of the preceding claims, **characterized** in that the porous scaffold is used as a bone regeneration promoting device in the new formed tissue.

L3

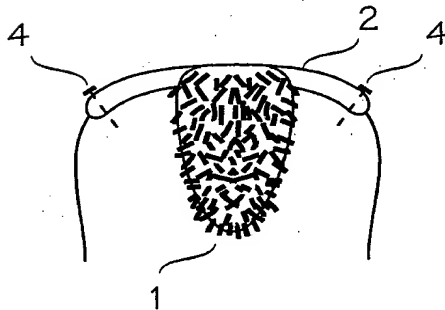
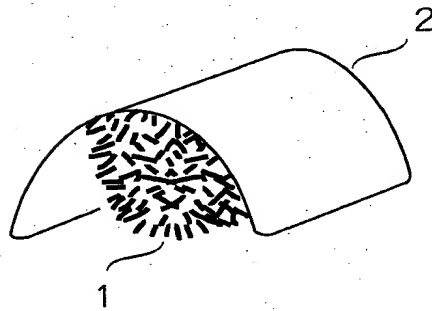
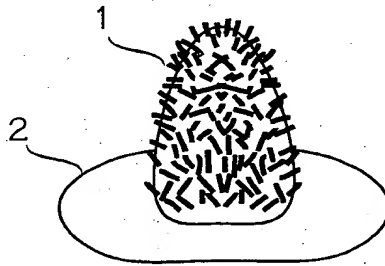
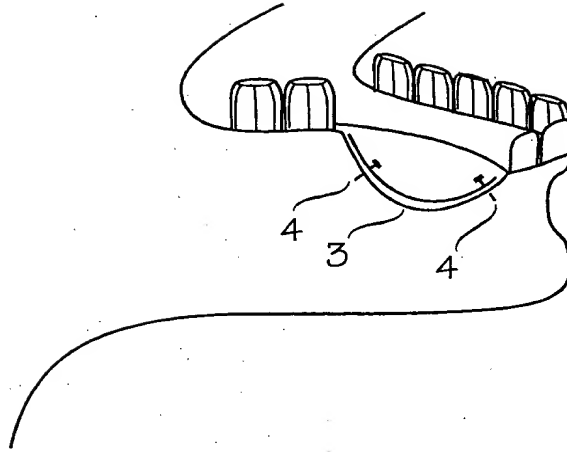
Abstract

Invention relates to porous bone filling materials prepared by sintering bioactive glass fibers in order to achieve a three dimensional block with interconnecting porosity. Due to the osteoconductive properties the bioactive glass fibers have the formed block is an ideal scaffold for new tissue (e.g. bone or cartilage) formation to occur. Porosity as high as 90 vol-% can be achieved by adjusting the manufacturing parameters. Strong porous blocks can be prepared for load bearing applications as well by adjusting the manufacturing parameters.

(Figure)

1/2
L4

Fig. 1



2/2
L4

Fig. 2

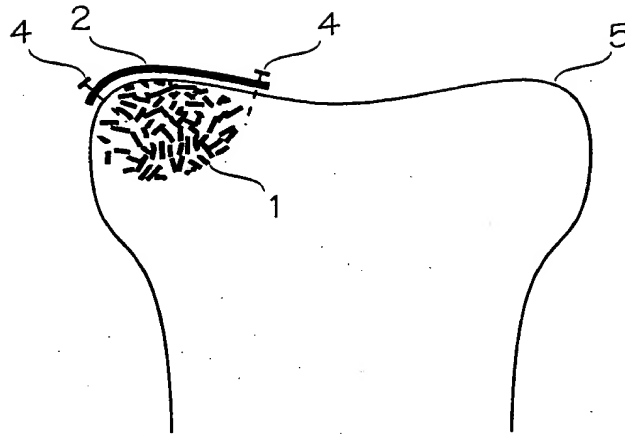


Fig. 3

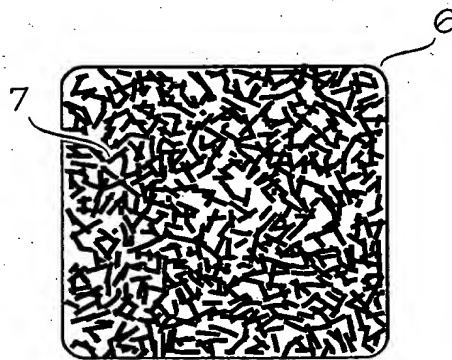


Fig. 4

